

REMARKS

Status of the Claims

Claims 1, 3-13 and 15-30 are pending in the application. Claims 2 and 14 are cancelled. Claims 15 and 19-29 have been withdrawn pursuant to a restriction requirement. Thus, Claims 1, 3-13 and 16-18 and 30 are presented for examination.

Withdrawal of Rejection

Applicant notes, with thanks, the withdrawal of the prior rejection of claims 1, 3-13, 16-18 and 30.

Claim Objection

Claim 7 is objected to. This objection is respectfully traversed. Moreover, this objection is moot in view of the above amendment of claim 7.

35 USC 112, Second Paragraph

Claims 1, 3-13, 16-18 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully traverses this rejection.

Moreover, this objection is moot in view of the above amendment of claim 1 in which the claim has been amended in a fashion that reflects the Examiner's (correct) interpretation of the claim.

35 USC 103(a) – Pinchuk, Li and Dinh

Claims 1, 3-13, 16-18 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al., US 2002/0107330 (Pinchuk), and further in view of Li et al., US 2003/0224033 (Li) and Dinh et al., US 5,571,166 (Dinh). Applicant respectfully traverses this rejection.

Moreover, it is noted that Li did not publish until December 4, 2003—a date subsequent to the filing date of the present application. Thus, this patent falls within the confines of subsection (e) of 35 U.S.C. § 102.

It is further noted that the assignee of Li and the assignee of the present application are one and the same (Boston Scientific Scimed, Inc.). 35 U.S.C. § 103(c) reads as follows: “Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.”

Statement concerning common ownership

In this regard, and in compliance with M.P.E.P. 706.02(I)(2), it is submitted that the present Application No. 10/632,054 and U.S. Pub. No. 2003/0224033 (Li) were, at the time the claimed invention of Application No. 10/632,054 was made, both owned by the same person or subject to an obligation of assignment to the same person.

Consequently, the subject matter of Li does not preclude patentability under 35 USC 103(a). Reconsideration and withdrawal of the rejection under 35 U.S.C. 103(a) over Pinchuk in view of Li and Dinh is respectfully requested.

Provisional Double Patenting Rejection—Strickler

Claims 1, 3-13, 16-18 and 30 are rejected on the ground of provisional non-statutory obviousness-type double patenting on the basis of claims 1-23 of Strickler et al, U.S. Patent Application Serial No. 10/894,400 (“Strickler”). This rejection is respectfully traversed.

As an initial matter it is noted that Application Serial No. 10/894,400 has issued as U.S. Patent No. 7,713,539.

With regard to the claim rejection based on Strickler, it is respectfully submitted that the claims of Strickler are directed to *radiation stable* copolymers and are thus the very antithesis of the polymers in the present claims, which are directed to homopolymers and copolymers that

comprise *radiation sensitive* groups that undergo a reduction in molecular weight upon treatment with radiation.

Reconsideration and withdrawal of the obviousness-type double patenting rejection based on Strickler is requested.

Provisional Double Patenting Rejection—Richard I

Claims 1, 3-13, 16-18 and 30 are rejected on the ground of provisional non-statutory obviousness-type double patenting on the basis of claims 1 and 4-23 of Richard et al, U.S. Patent Application Serial No. 10/632,008 (“Richard I”).

As an initial point, it is noted that this rejection is a *provisional* rejection and is thus not ripe for rational argument at this point because the claims of 10/632,008 have not issued. As noted in MPEP 804 I B (emphasis added): “Occasionally, the Examiner becomes aware of two copending applications...that would raise an issue of double patenting *if one of the applications became a patent*. ... The merits of such a provisional rejection can be addressed by both the applicant and the Examiner without waiting for the first patent to issue.” Thus, Applicant has the right to address the provisional double patenting rejections at a later date, when and if the double patenting rejections are the only rejections remaining in the subject applications. See in particular MPEP 804.I.B.1.

Moreover, with regard to the merits of the claim rejection based on claims 1 and 4-23 of Richard I, it is respectfully submitted that the claims of Richard I pertain to a polymeric release region comprising a silicone copolymer comprising a plurality of siloxane units and a plurality of non-siloxane units. It is not seen how these claims are pertinent to those presently claimed, particularly since the claims of Richard I do not recite *radiation sensitive* groups. Indeed, one of the objectives of Richard I is to produce devices that are *radiation resistant* such that they can undergo radiation sterilization. See paragraph [0016].

In view of the foregoing, withdrawal of the double patenting rejection based on Richard I is requested.

Double Patenting Rejection—Richard II

In the current Office Action, the Examiner has rejected Claims 1, 3-13, 16-18 and 30 on the ground of non-statutory obviousness-type double patenting on the basis of claims 1-24 of Richard et al U.S. Patent No. 7,241,455 (formerly cited as U.S. Patent Application Serial No. 10/409,358 (“Richard II”). This rejection is respectfully traversed.

Claim 1 of Richard II provides for:

1. An implantable or insertable medical device comprising (a) a therapeutic agent and (b) a polymeric release region that controls the release of said therapeutic agent upon administration to a patient, wherein said polymeric release region comprises a radiation-crosslinked polymer that is crosslinked without a crosslinking agent, wherein said radiation-crosslinked polymer is a radiation-crosslinked methylene-containing polymer that is formed from one or more hydrocarbon monomers and wherein said polymeric release region is crosslinked with a radiation dose of at least 10,000 rads.

It is a basic principle of polymer chemistry that crosslinking builds molecular weight. In contrast to Richard II, the present invention teaches the opposite of crosslinking, and describes using radiation sensitive groups to reduce molecular weight in the polymeric release region.

The Examiner has responded by arguing that although the methylene-containing polymers are crosslinked by radiation, the polymeric release regions of Richard II “allows for inclusion of block copolymers (see claim 21).” The Examiner further argues that since there is no indication in the patented claims that only the methylene-containing polymers in the polymeric release region are treated with radiation, the claims are construed to include the exposure of block copolymers containing region in the polymeric release region to radiation. The Examiner concludes that this radiation treatment of the block copolymers would (inherently) result in reducing the molecular weight of the polymer.

Applicant respectfully disagrees. For example, even assuming that the block copolymers were exposed to radiation, there is no reason to believe that the block copolymers would be reduced in molecular weight. For example, the block copolymers may comprise non-methylene-containing polymer blocks that are radiation stable or radiation-crosslinkable.

Furthermore, instant claims 1, 3-13, 16-18 and 30 require a polymer selected from the group consisting of homopolymers and copolymers comprising polytetrafluoroethylene, collagen, cellulose, polyisobutylene, poly(2-methyl butane), or poly(2-methyl pentene) which are unobvious in view of claims 1-24 of Richard II.

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Thus, the double patenting rejection should be withdrawn.

Conclusion

Should the Examiner be of the view that an interview would expedite consideration of the application, request is made that the Examiner telephone Applicant's attorney at (703) 433-0510 in order to resolve any outstanding issues.

Respectfully submitted,

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/David B. Bonham/

Attorney for Applicant
Mayer & Williams, PC
251 North Avenue West, 2nd Floor
Westfield, NJ 07090
Tel.: 703-433-0510
Fax: 703-433-2362

David B. Bonham

Registration No. 34,297